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EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,243

Applicant(s)

BARDY, GUST H.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/15/03 (Amendment and Term. Disclaimer).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-14, 16-23, 25-28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-14, 16-23, 25-28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Applicant amended the claims to overcome the rejection of record, hence a new ground of rejection is established in the subsequent paragraphs.

Since the new rejection utilizes many of the same references, the following general comment is offered. The Applicant's arguments filed 8/15/03 have been fully considered.

In response to the Applicant's argument that the references fail to show certain features of the Applicant's invention, it is noted that the features upon which applicant relies (i.e. on going or substantially continuous monitoring) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Terminal Disclaimer

2. The terminal disclaimer filed on 8/15/03 disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of U.S. Patent No. 6277072 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-5, 7-14, 16-23, 25-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner finds in the specification the “collected information” is used to “follow the medical well being of a patient and can recognize any trends... that might warrant medical intervention” (page 15, lines 7-9), but the Examiner is unable to find support for the newly added limitation, “for evaluating an absence, an onset, a progression, a regression and a status quo of the patient status” in the specification. New matter may not be added at this point in the prosecution. Appropriate correction is required.

5. Claims 1-5, 7-14, 16-23, 25-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner is unable to find reference in the specification “for evaluating an absence, an onset, a progression, a regression and a status quo of the patient status” in the specification. It appears the specification does not disclose what criteria are used, how a “substantially non-conforming measure” relates, and how the evaluation is performed to determine an absence, an onset, a progression, a regression and a status quo of the patient status. Appropriate correction is required.

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6. Claims 19 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 19 and 30 are unclear because each references as a claimed element a cancelled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. Claims 1-5 and 10-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson (US 6155267).

As to claims 1, 2, 10, and 11, chronic data from at least one sensor is monitored by the monitoring software (56) to establish a baseline. Periodically, chronic data is monitored to detect a change in state from the baseline (col. 2 @ 53-64). Substantial nonconforming measures are identified and indicted by a communication signal or an alarm (read as a patient status indicator) (col. 10 @ 2-13). The monitoring device is an implantable medical device (12 (col. 4 @ 49-53). Data comparison evaluates a change in state of the patient, read as “an absence, an onset, a progression, a regression, and a status quo of patient status” (col. 2 @ 59-64).

As to claims 3 and 12, the alarm is read as feedback (col. 10 @ 11-20).

As to claims 4 and 13, the oxygen sensor data (the reference feedback) and the pressure sensor (the physiological measure) are monitored by the system (col. 10 @ 28-41).

As to claims 5 and 14, the reference baseline is periodically revised (col. 8 @ 12-16).

Claim Rejections - 35 USC § 103

8. Claims 1-5, 10-14, 20-23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selker et al. (US 5724983) in view of Heemels et al. (US 5603331) and further in view of Brown (US 6168563).

Selker et al. disclose continuous monitoring using a predictive instrument.

As to claims 1-3 and 10-12, one or more clinical features (read as physiological measures) are monitored periodically to compute a change-of-condition measure (read as a patient status indicator). If the change-of-condition measure is above a threshold, an alarm notification (automated feedback) is generated (col. 1 @ 61 – col. 2 @ 11; col. 3 @ 55 – col. 4 @ 65). The monitoring device can be from a wide variety of monitoring devices including heart rate monitors (col. 12 @ 38-42).

As to claim 4 and 13, S-T segment depressions and elevations (the reference feedback) and the ECG wave (the physiological measure) are monitored by the system (col. 2 @ 54-60).

As to claims 5 and 14, the reference baseline is periodically revised (col. 5 @ 8-18).

As discussed in the previous four paragraphs of this action, Selker et al. disclose the claimed invention except for the monitoring device being implantable.

Heemels et al. teach cardiac data analysis using an implantable medical device (2) for the purpose of monitoring and collecting data such as heart rate variability. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an implantable medical device in the Selker et al. system in order to provide an alternate form for

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the cardiac data monitoring and collection device so the essential cardiac data collected and processed is disseminated to the care professional enabling diagnosis and prognosis (abstract; figure 2; col. 1 @ 59-61; col. 2 @ 13-33).

As discussed in the previous paragraph of this action, modified Selker et al. disclose the claimed invention except for: 1) storing all monitored data, and 2) monitoring and recording quality of life measurements.

Brown discloses remote health monitoring.

As to storing data, Brown teaches health monitoring using memory for the purpose of storing all collected data. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used memory to store all the data in the modified Selker et al. system in order to enable the health care provider to review the data in its entirety, record the data for later use, and/ or use the data to perform various analyses (col. 9 @ 2-19; col. 9 @ 61 – col. 10 @ 2).

As to the quality of life measurements, Brown teaches health monitoring using quality of life measurements for the purpose adding the subjective patient perspective information to the simultaneously measured physiological parameters so the caregiver has a more comprehensive understanding of the patient's condition. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used quality of life measurements in the modified Selker et al. system to enable the health care provider to more optimally monitor and manage the health care condition of the patient (abstract; figures 13 and 16; col. 6 @ 4-7; col. 9 @ 20-60).

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9. Claims 7-9 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selker et al. (US 5724983) in view of Heemels et al. (US 5603331) and further in view of Brown (US 6168563) and further in view of Levine (US 4852570). As discussed in paragraph 8 of this action, modified Selker et al. disclose the claimed invention except for monitoring a prescribed exercise session and identifying abnormal activity or exercise.

Levine teaches medical physical analysis using a prescribed exercise session for the purpose of identifying abnormal activity or exercise indicative of illness or malfunction. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used monitoring of prescribed exercise sessions to identify abnormal activity or exercise in the modified Selker et al. system in order to provide an alternate measure that identifies long-term changes or trends in a patient's health (abstract; col. 10 @ 59 – col. 12 @ 38).

10. Claims 19 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selker et al. (US 5724983) in view of Heemels et al. (US 5603331) in view of Brown (US 6168563) and further in view of Levine (US 4852570) and further in view of Selker et al. (US 6067466). As discussed in paragraphs 8 and 9 of this action, modified Selker et al. (US 5724983) disclose the claimed invention except for providing a computer-readable storage medium holding code for performing the methods of this invention.

Selker et al. (US 6067466) teach computer program transfer using a computer readable medium for the purpose of entering an analysis/ diagnostic program in a processing module or computer. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a computer readable medium in the modified Selker et al. (US 5724983)

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system in order to provide a typical means of entering the analysis/ diagnostic program into a computer so the program is efficiently and effectively read/ loaded into the processor module/ computer (col. 3 @ 27-37 and 54-57).

Specification

10. The amendment filed 8/15/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "for evaluating an absence, an onset, a progression , a regression and a status quo of the patient status".

Applicant is required to cancel the new matter in the reply to this Office Action.

Statutory Basis

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

380
9-15-03

Angela D. Sykes

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